

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
 )  
SHEILA BROWN, et al. )  
 )  
v. )  
 )  
AMERICAN HOME PRODUCTS )  
CORPORATION ) NO. 99-20593

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8439

Bartle, C.J.

March 24, 2010

Lorraine M. Fengel ("Ms. Fengel" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Gale B. Fengel, Ms. Fengel's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Randall G. Johnson, M.D. Based on an echocardiogram dated July 20, 2001, Dr. Johnson attested in Part II of Ms. Fengel's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%.<sup>4</sup> Based on such

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3. (...continued)  
for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Johnson also attested that Ms. Fengel suffered from New (continued...)

findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$415,893.<sup>5</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Subhash J. Patel, M.D., F.A.C.C., did not specify a percentage as to claimant's ejection fraction. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In March, 2006, the Trust forwarded the claim for review by David I. Silverman, M.D., one of its auditing cardiologists. In audit, Dr. Silverman concluded that there was no reasonable medical basis for the attesting physician's conclusion that claimant had a reduced ejection fraction. In support of this conclusion, Dr. Silverman explained that the "[ejection fraction] is clearly >65% by multiple methods. [Ejection fraction] is listed as 'normal' in the echo report. No actual number is given."

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4. (...continued)

York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is claimant's ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim.

Based on the auditing cardiologist's finding that claimant did not have a reduced ejection fraction, the Trust issued a post-audit determination denying Ms. Fengel's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that the "calculation of a patient's ejection fraction via two-dimensional echocardiography is highly subjective, with inter-reader variability of up to 10% being the norm."<sup>7</sup> Thus, according to claimant, there is only "a very slight difference of opinion" between the attesting physician and the auditing cardiologist.<sup>8</sup> Finally, claimant suggested that the Trust did

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Fengel's claim.

7. In support of this argument, claimant submitted three (3) medical articles.

8. Claimant also contended that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had any "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not established how those filings entitle her to Matrix Benefits, they are not pertinent to disposition of

(continued...)

not properly apply the "reasonable medical basis" standard established in the Settlement Agreement as the auditing cardiologist simply substituted his opinion for that of the attesting physician.<sup>9</sup>

The Trust then issued a final post-audit determination again denying Ms. Fengel's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Fengel's claim should be paid. On October 19, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6619 (Oct. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 22, 2007, and claimant submitted a sur-reply on February 28, 2007. The Show

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8. (...continued)  
this show cause claim.

9. In support of this argument, claimant refers to Dr. Silverman's conclusion in connection with another show cause claim. As the issue is whether Ms. Fengel has established a reasonable medical basis for her claim, claimant's reliance on the auditing cardiologist's conclusion as to a different claimant is misplaced, particularly where that conclusion did not relate to a claimant's ejection fraction but rather the complicating factor of an abnormal left atrial dimension.

Cause Record is now before the court for final determination.

See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

In support of her claim, Ms. Fengel reasserts the arguments that she made in contest. Claimant further contends that "there is typically a 7-10% variation in calculating a patient's ejection fraction," and "the 5% difference between the attesting cardiologist's 60% ejection fraction and the auditing cardiologist's 65% ejection fraction falls within the normal range of inter-reader variability." As a result, "[n]either diagnosis is correct or incorrect; both fall within the realm of having a 'reasonable medical basis.'"<sup>10</sup>

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10. Claimant also asserts that Dr. Silverman may have reached his determination regarding claimant's ejection fraction based on a misinterpretation of the Green Form. According to claimant, (continued...)

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard and contends that the auditing cardiologist properly applied the reasonable medical basis standard. Moreover, the Trust argues that claimant did not rebut Dr. Silverman's specific finding. Finally, the Trust asserts that the concept of inter-reader variability does not establish a reasonable medical basis for Ms. Fengel's claim.

In her sur-reply, claimant reasserts that the auditing cardiologist "either misunderstands or is refusing to apply the concept of inter-reader variability and therefore is not applying the reasonable medical basis standard" and that the auditing cardiologist may have misinterpreted the issue because of the Green Form format.

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10. (...continued)  
"if the auditing cardiologist did not understand the minutia of the Settlement Agreement, he might erroneously mark on his Audit Report that 50%-60% is medically unreasonable while, if asked, conceding that 60% would be medically reasonable." Claimant further asserts that the auditing cardiologist "might believe that a claimant has to have (or should be required to have) an abnormal ejection fraction in order [to] qualify for matrix-level benefits" and, according to claimant, an ejection fraction of 50%-60%, although a complicating factor under the Settlement Agreement, is nevertheless often considered a "normal" ejection fraction. Thus, claimant asserts that "it is not for the auditing cardiologists to re-define the terms of the Settlement Agreement." We reject these arguments. Given that Dr. Silverman specifically determined that claimant's ejection fraction was greater than 65%, nothing suggests that he "misinterpreted" the Green Form or "re-define[d]" the Settlement Agreement's definition of a reduced ejection fraction for a mitral valve claim.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest Dr. Silverman's determination as to her ejection fraction. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Fengel rests only on Dr. Johnson's check-the-box diagnosis on her Green Form. Ms. Fengel does not identify any particular error in Dr. Silverman's measurements or conclusions. Mere disagreement with the auditing cardiologist is insufficient to meet a claimant's burden of proof. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Silverman determined in audit, and Ms. Fengel does not adequately dispute, that the attesting physician's finding of a reduced ejection fraction was erroneous and that claimant's ejection fraction was greater than 65% "by multiple methods." Contrary to claimant's argument, Dr. Silverman properly applied the reasonable medical basis standard established under the Settlement Agreement. When, as here, an auditing cardiologist specifically determines that

multiple methods of evaluation demonstrate a claimant does not have a reduced ejection fraction in the range required under the Settlement Agreement for a mitral valve claim, a claimant may not merely rest or rely on the Green Form.<sup>11</sup>

Finally, we reject claimant's argument that inter-reader variability accounts for the difference in the opinions of the attesting physician and auditing cardiologist. More specifically, the court does not accept claimant's assertion that, for purposes of establishing a reasonable medical basis for a reduced ejection fraction, the court should assume inter-reader variability of between 7% and 10%. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of a reduced ejection fraction in the range of 50% to 60% cannot be medically reasonable where the auditing cardiologist concluded that claimant's ejection fraction was greater than 65% using multiple methods of evaluation. To conclude otherwise would allow a claimant, for purposes of a mitral valve claim, to

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11. For this reason as well, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Silverman merely substituted his opinion for that of the attesting physician. Instead, Dr. Silverman specifically found that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction because claimant's ejection fraction was greater than 65%. Neither claimant nor claimant's attesting physician, however, adequately refuted or responded to this determination.

receive Matrix Benefits even where the ejection fraction was as high as 67% or 70%. This result would render meaningless the standards established in the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Fengel's claim for Matrix Benefits and the related derivative claim submitted by her spouse.